No. 2023-1169

United States Court of Appeals for the Federal Circuit

AMARIN PHARMA, INC., AMARIN PHARMACEUTICALS IRELAND LIMITED, MOCHIDA PHARMACEUTICAL CO., LTD.,
Plaintiffs-

Appellants v.

HIKMA PHARMACEUTICALS USA INC., HIKMA PHARMACEUTICALS PLC,
Defendants-Appellees

HEALTH NET LLC,
Defendant

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE,
CASE NO. 1:20-CV-01630-RGA-JLH, JUDGE RICHARD G. ANDREWS

BRIEF FOR THE ASSOCIATION FOR ACCESSIBLE MEDICINES AS *AMICUS CURIAE* IN SUPPORT OF THE PETITION FOR REHEARING EN BANC

MATTHEW S. HELLMAN
HALEY B. TUCHMAN
JENNER & BLOCK LLP
1099 New York Ave., NW
Suite 900
Washington, DC 20001
(202) 639-6000

Counsel for Amicus Curiae

September 5, 2024

CERTIFICATE OF INTEREST

Counsel for *Amicus Curiae* Association for Accessible Medicines certifies the following:

1. **Represented Entities.** Fed. Cir. R. 47.4(a)(1). Provide the full names of all entities represented by undersigned counsel in this case:

Association for Accessible Medicines.

2. **Real Party in Interest.** Fed. Cir. R. 47.4(a)(2). Provide the full names of all parties in interest for the entities. Do not list the real parties if they are the same as the entities:

N/A

3. **Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3). Provide the full names of all parent corporations for entities and all publicly held companies that own 10% or more stock in the entities:

N/A

4. **Legal Representatives.** List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

N/A

5. **Related Cases.** Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b):

N/A

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

N/A

September 5, 2024

/s/ Matthew S. Hellman

Matthew S. Hellman
JENNER & BLOCK LLP
1099 New York Ave., NW
Suite 900
Washington, DC 20001
(202) 639-6000

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

INTEREST OF *AMICUS CURIAE*

The Association for Accessible Medicines ("AAM") is a nonprofit, voluntary association representing manufacturers and distributors of generic and biosimilar medicines and bulk active pharmaceutical chemicals, as well as suppliers of other goods and services to the generic pharmaceutical industry. AAM's members provide patients with access to safe and effective generic and biosimilar medicines at affordable prices. AAM's core mission is to improve the lives of patients by providing timely access to safe, effective, and affordable prescription medicines.

Generic drugs constitute 90% of all prescriptions dispensed in the United States, yet account for less than 18% of prescription drug spending.[1] Savings attributable to generics and biosimilars have kept nearly $2.9 trillion in the pockets of patients and taxpayers over the past ten years.[2]

AAM regularly participates in litigation as *amicus curiae*, including in several cases concerning the skinny label provisions at issue in this matter.

[1] Ass'n for Accessible Meds., *2023 The U.S. Generic & Biosimilar Medicines Savings Report* (Sept. 2023), https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf.
[2] *Id.*

INTRODUCTION

Forty years ago, Congress enacted the section viii carve-out in the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"). Its goal was simple: to ensure efficient patient access to low-cost generic and biosimilar medicines by protecting generic drug companies from infringement lawsuits. But what began as a shield, "a way for generics to *avoid* inducement liability—and thus litigation itself," has become a sword that is being wielded against the very generics the law was intended to protect. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 25 F.4th 949, 955 (Fed. Cir. 2022) ("*GSK Rehearing*") (Prost, J., dissenting, joined by Dyk and Reyna, JJ.).

The panel's decision makes it all but impossible to market a generic, section viii drug without infringement risk. This case presents one of the most benign factual scenarios imaginable, and yet the panel's decision still creates substantial risk of liability. It was undisputed here that the generic had carved-out infringing uses from its label and it was undisputed that the generic's label did not induce infringement as a matter of law. Yet the panel held that simply calling a product a "generic" drug and referencing the total market size of the brand drug is sufficient, in "totality," to show *active* inducement. To make things worse, the decision provides no guidance to generic manufacturers seeking to avoid inducement liability in future cases. The skinny label path is now narrowed to the vanishing point, and fraught with costly

uncertainty at a time when generics already face immense market challenges. The effects of this decision will be felt throughout the industry, most notably by the patients who will lose access to low-cost generic medicines.

Simply put, section viii has been turned on its head. The Court should grant rehearing en banc to restore the protections that Congress intended generics to have.

ARGUMENT

I. The Panel's Decision Destroys Generic Manufacturers' Section VIII Protections.

Despite assertions otherwise, *see* Op. 12–13, this is still a section viii case.[3] Section viii carve outs were designed to "speed the introduction of low-cost generic drugs to market." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012). To accomplish that, section viii intended to afford certainty to generic manufacturers that they would "*avoid* inducement liability" if they properly carved out infringing uses. *GSK Rehearing*, 25 F.4th at 955 (Prost, J., dissenting). Over the years, section viii has done just that—allowing "generic drugs to be approved for sale an average of three years before the relevant method-of-use patents expired."[4] Generic approvals have also had tremendous market effects. FDA

[3] The panel provides no reason why section viii's skinny label protections should be less effective for generics post-launch.

[4] Brief for the United States as Amicus Curiae, *Teva Pharms. USA, Inc. v. GlaxoSmithKline LLC*, 143 S. Ct. 2483 (2023) (No. 22-37), 2023 WL 2717391, at *21 (citing Bryan S. Walsh et al., *Frequency of First Generic Drug Approvals With 21 'Skinny Labels' in the United States*, 181 JAMA Internal Med. 995, 995 (2021)).

estimates that "[g]eneric drugs approved between 2018 and 2020…have saved consumers more than $50 billion in the first 12 months of generic sales," and the approval of the first generic version of a brand-name drug, often with a carved-out condition of use, has reduced prices by more than 75 percent.[5]

But the panel's decision relies on an "implausible" premise to upend the entire statutory regime: "that Congress, when enacting the skinny-label provisions against the backdrop of the inducement statute, intended to put generics in th[e] position" of facing inducement liability even when they had indisputably "play[ed] by the skinny-label rules." *GSK Rehearing*, 25 F.4th at 955 (Prost, J., dissenting). That understanding of section viii is contradicted by its goal of facilitating the "approval of generic drugs as soon as [the] patents allow." *Caraco*, 566 U.S. at 405.

Choosing to roll the skinny-label dice will open generics up to tremendous liability. "Generics sell their products for considerably less than brands, so a jury's award of lost profits to the brand can dwarf whatever profits a generic could make." *GSK Rehearing*, 25 F.4th at 955 (Prost, J., dissenting). And even if inducement liability is ultimately never imposed, holding that Amarin's complaint plausibly stated a claim for induced infringement endorses an entire class of litigation that section viii carve outs were meant to deter. The risks stemming from an inability to

[5] *Id.* at 20 (citing Ryan Conrad et al., FDA, *Estimating Cost Savings from New Generic Drug Approvals in 2018, 2019, and 2020*, at 3–4 (2022)).

resolve a case at the motion to dismiss stage are not "inflated characterizations." Op. 20. With the average cost of defending a patent infringement lawsuit hovering around $3.5 million, the expense of litigating through summary judgment will be a costly albatross around the necks of generics.[6] And the "safeguard" of settling or prevailing at summary judgment has been rejected by the Supreme Court as no safeguard at all. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558–59 (2007).

Even then, despite indications that Hikma could easily win at summary judgment, *see* Oral Arg. 22:37–24:45, there is no guarantee that Hikma would be afforded that intermediate opportunity to prevail. In Delaware—one of the most common forums for pharmaceutical litigation—"judges rarely entertain" summary judgment motions.[7] Reading this decision in combination with *GSK* reveals additional cause for concern. Once a case like this makes it to a jury, both the district judge and this Court will be extremely reluctant to overturn an infringement verdict.

In short, the decision destroys the brightline that once enabled generics to avoid inducement liability and replaces it with a minefield of uncertainty. The panel's only forward-looking guidance is that "clarity and consistency in a generic

[6] G. Day & S. Udick, *Patent Law and the Emigration of Innovation*, 94 Wash. L. Rev. 119, 125 (2019).

[7] Katherine Rhoades, *Do Not Pass Go, Do Not Stop for Summary Judgment: The U.S. District Court for the District of Delaware's Seemingly Disjunctive Yet Efficient Procedures in Hatch-Waxman Litigation*, 14 Nw. J. Tech. & Intell. Prop. 81, 95 (2016).

manufacturer's communications regarding a drug marketed under a skinny label may be essential in avoiding liability for induced infringement." Op. 20. To the extent this provides any boundary at all, generic manufacturers cannot surmise what it would look like to be clear and consistent in a way that would enable them to prevail on a 12(b)(6) motion.

II. The Panel's Decision Contravenes Federal Circuit Inducement Precedent.

In addition to the reasons discussed *supra*, the panel's holding contradicts this Court's inducement decisions in a manner that warrants en banc review. This is not a case in which the panel found that Hikma attempted to but was unsuccessful in carving out Amarin's patented indications. That matters. Under this Court's precedents, the panel's infringement inquiry should have stopped once it determined that Hikma's label was skinny enough; it was improper to include the label as a factor in a "*totality*" consideration instead. *See* Op. 13.

The panel characterizes *GSK* as holding that "a generic manufacturer can be liable for inducing infringement of a patented method even if it has *attempted to* 'carve out' the patented indications from its label" when "other evidence is asserted with regard to inducement." Op. 14 (emphasis added) (citing *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1338 (Fed. Cir. 2021)). It is undisputed that in *GSK*, the generic manufacturer *did* carve out what FDA told it to, but regardless, as the panel properly recognized here, Hikma's "label does not, as a

matter of law, 'recommend[], encourag[e], or promot[e] an infringing use.'" Op. 16 (quoting *Amarin Pharma, Inc. v. Hikma Pharms. USA Inc.*, 578 F. Supp. 3d 642, 646 (D. Del. 2022)). Indeed, "even Amarin seem[ed] to agree that the label alone does not instruct infringement." Op. 19.

Those points are significant. When a court finds that a generic manufacturer's attempt to carve out a patented indication has been successful, the infringement inquiry should end; marketing materials cannot transform a label that does not actively induce infringement into one that does.

Amarin's case falls apart once this flaw is acknowledged. Amarin cannot plausibly state a claim for induced infringement when Hikma's actions—the only actions relevant to an inducement inquiry—include successfully carving out the infringing method. *See Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1331 (Fed. Cir. 2016) (explaining inducement requires that "the defendants' actions led to direct infringement" (quoting *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1274 (Fed. Cir. 2004))). Even assuming that physicians read Hikma's press releases or website as instructing that Hikma's "generic version" in the "broad therapeutic category of 'Hypertriglyceridemia'" can be prescribed for all approved uses of Vascepa, Op. 18, the physician would then consult *Hikma's* label, and they would see that the label does not "'recommend[], encourag[e], or promot[e] an infringing use,'" Op. 16 (quoting *Amarin Pharma*, 578

F. Supp. 3d at 646). In other words, Hikma's website and marketing materials cannot plausibly convert a non-infringing label into an infringing one, and they are entitled to no meaningful evidentiary weight.

To the extent Hikma's marketing materials contradict the label, there are numerous criminal and civil statutory penalties designed to deter that behavior. *See, e.g.*, 21 U.S.C. § 331(a). But Congress never intended to provide for inducement liability when the skinny label process has yielded precisely what it is supposed to: a non-infringing label.

III. The Decision Will Have Broad Implications for Generic Drugs.

Brand-name drugs are the obvious beneficiaries of this reimagined statutory regime. Patients, on the other hand, will suffer. Now that section viii affords essentially no "security from label-based liability," brands' ability to delay (and in some cases, shut out) generic competition has been supercharged. *GSK Rehearing*, 25 F.4th at 955 (Prost, J., dissenting).

Without a clear skinny-label pathway, generics will be disinclined to use section viii, allowing brands to "maintain de facto indefinite exclusivity over a pharmaceutical compound by obtaining serial patents for approved methods of us[e]." *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1380 (Fed. Cir. 2012). Not only will patients be forced to pay higher brand prices for even longer, they may be deprived of access to life-saving alternatives altogether if a generic is

never developed.

Paragraph IV challenges are also less likely in a world of weakened skinny label protections. The number of patents protecting a brand drug is often high.[8] If, despite a successful Paragraph IV challenge to other Orange Book-listed patents, generic manufacturers cannot rely on the certainty of a carve-out to market a product, Paragraph IV challenges will dwindle because method of use patents will block what were once-viable section viii carve-outs.

The tremendous implications of this decision are not "limited to the allegations" of this case, nor can they be blamed on "the standard of review appropriate for this stage of proceedings." Op. 20. The facts here are not so rare—they are and will be the facts of almost *every* skinny label case, as the phrase "generic version" is how generic drugs are referred to in the industry. *See, e.g.*, 21 U.S.C. § 353d(a)(3); Hikma Reh'g Br. 13. So too, referring to a drug as "AB-rated" is not meaningfully different from referring to it as a "generic version."[9] *See* Op. 18–19.

Given these realities, it is easy to see how generics could conclude that the

[8] "As of July 2022, Amarin ha[d] sixty-eight patents listed in the Orange Book for the Vascepa product." S. Tu & C. Duan, *Pharmaceutical Patent Two-Step: The Adverse Advent of Amarin v. Hikma Type Litigation*, 12 NYU J. Intell. Prop. & Ent. L. 1, 26 (2022).

[9] Both phrases are used interchangeably. Brief for United States, *supra* note 4 at 17 n.5 (referring to a drug as AB-rated "simply reflect[s] the truism that a generic drug is required to be therapeutically equivalent to its brand-name reference drug if used as directed on the labeling").

outsized threat of protracted, resource-intensive litigation without the prospect of a 12(b)(6) resolution makes it far too risky to gamble on section viii approval. The same is true for Paragraph IV statements challenging other Orange Book-listed patents. Predictions that generics "simply won't play" are dramatically heightened as a result of this decision. *GSK Rehearing*, 25 F.4th at 955 (Prost, J., dissenting). The Court should review this case en banc to restore the balance initially intended by section viii's protections.

CONCLUSION

For the foregoing reasons, AAM requests that the Court grant Hikma's petition for rehearing en banc.

Respectfully submitted,

/s/ Matthew S. Hellman
Matthew S. Hellman
Haley B. Tuchman
JENNER & BLOCK LLP
1099 New York Ave., NW
Suite 900
Washington, DC 20001
(202) 639-6000

Counsel for Amicus Curiae

Dated: September 5, 2024

CERTIFICATE OF SERVICE

I certify that true and correct copies of the foregoing *Brief for Association for Accessible Medicines as Amicus Curiae* were served on September 5, 2024 on all counsel of record by the CM/ECF system.

September 5, 2024

/s/ Matthew S. Hellman
Matthew S. Hellman
JENNER & BLOCK LLP
1099 New York Ave., NW
Suite 900
Washington, DC 20001
(202) 639-6000

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Circuit Rule 35(g)(3) because it contains 2,259 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2).

2. This brief complies with the typeface requirements of Federal Circuit Rule 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in 14-point Times New Roman, a proportionally spaced typeface, using Microsoft Word.

September 5, 2024

/s/ Matthew S. Hellman

Matthew S. Hellman
JENNER & BLOCK LLP
1099 New York Ave., NW
Suite 900
Washington, DC 20001
(202) 639-6000